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EXAMINER	
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ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,404	MORIYAMA, HIROKI	
	Examiner	Art Unit	
	MATTHEW J. KASZTEJNA	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on October 29, 2008, amended claims 1 and 3-4 and new claim 20 are acknowledged. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 and 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,690,175 to Ouchi et al. in view of U.S. Patent No. 5,916,147 to Boury.

In regards to claims 1-2 and 17, Ouchi et al. a flexible tube for use in an endoscope comprising: an insertion unit having a soft portion; a small-diameter portion 3c which is included in the soft portion and whose outer diameter is *substantially* the same over the whole length thereof; a large-diameter portion 3f which is formed on the operator side of the soft portion opposite the small-diameter portion and whose outer diameter is larger than the outer diameter of the small-diameter portion; and a tapered portion 3d-e linking the small-diameter portion and the large-diameter portion, and a sheathing resin that is an integral member having a thickness which is varied in order to form the small-diameter portion, the large-diameter portion and the tapered portion (see Fig. 5 and Col. 7, Lines 9-35). Furthermore, Ouchi et al. teach of a flexible tube relating

generally to flexible tubes for endoscopic devices having improved flexibility, torsional rigidity and resistance to compression for facilitating insertion of the tube into the body cavity but are silent with respect to the insertion portion having an articulating section at the distal end of the endoscope and a control section disposed at the proximal end of the insertion unit for controlling articulation of the articulating section. Ouchi et al. teach of a manipulating unit at the proximal end of the apparatus (see Col. 7, Lines 48-52) but are silent with respect to the unit being used specifically for controlling the articulating section of the insertion unit. Boury teaches of an analogous apparatus comprising a catheter which can be manipulated by a physician even after the catheter is placed into the patient's body. The catheter includes an elongate tubular member which has a proximal end, a distal end, a remotely manipulable length, and a wall defining a lumen. The catheter also includes first and second wires slidably retained by the wall and extending proximally beyond the proximal end of the tubular member. The first wire is attached adjacent a distal end thereof to the wall at a first node located along the manipulable length. The second wire is attached adjacent a distal end thereof to the wall at a second node located along the manipulable length, with the second node being located distally of the first node along the manipulable length of the tubular member (see Figs. 1-3 and Col. 2, Line 53 – Col. 3, Line 25). Boury demonstrates that it is well known within the art to provide endoscopic devices with control means to facilitate insertion of the flexible tube within the body. Thus, It would have been obvious to one skilled in the art at the time the invention was made to provide the apparatus of Ouchi et al. with an articulating section and a control section to control the insertion section, thus

allowing a physician to shape a length of the tube and to permit it to be more readily positioned within a body channel of the patient as taught by Boury and is well known within the art. Furthermore, Boury teaches that the overall length of the insertion tube may be varied as necessary, from 50-150 cm (see Col. 4, Lines 6-20). Thus the tapered portion would be located forward an endoscope portion located 70cm from the distal end.

Claims 1-4 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,690,175 to Ouchi et al. in view of U.S. Patent No. 5,083,549 to Cho et al.

In regards to claims 1-4 and 17, Ouchi et al. a flexible tube for use in an endoscope comprising: an insertion unit having a soft portion; a small-diameter portion 3c which is included in the soft portion and whose outer diameter is *substantially* the same over the whole length thereof; a large-diameter portion 3f which is formed on the operator side of the soft portion opposite the small-diameter portion and whose outer diameter is larger than the outer diameter of the small-diameter portion; and a tapered portion 3d-e linking the small-diameter portion and the large-diameter portion, and a sheathing resin that is an integral member having a thickness which is varied in order to form the small-diameter portion, the large-diameter portion and the tapered portion (see Fig. 5 and Col. 7, Lines 9-35). Furthermore, Ouchi et al. teach of a flexible tube relating generally to flexible tubes for endoscopic devices having improved flexibility, torsional rigidity and resistance to compression for facilitating insertion of the tube into the body cavity but are silent with respect to the insertion portion having an articulating section at

the distal end of the endoscope and a control section disposed at the proximal end of the insertion unit for controlling articulation of the articulating section. Ouchi et al. teach of a manipulating unit at the proximal end of the apparatus (see Col. 7, Lines 48-52) but are silent with respect to the unit being used specifically for controlling the articulating section of the insertion unit. Cho et al. teach of an analogous endoscope comprising a flexible tip 29 which is deflectable by controls in the handle 12 (see Figs. 6-7). When the user moves the control 51 in one direction, one spring guide wire 43 (42) is placed under tension and pulls tip end 29 to the side to which that spring guide wire is attached. When the user moves control 51 in an opposite direction, the second spring guide wire 42 (43) placed under tension and the other spring guide wire 42 (43) is released. Flexible tip 29 then straightens to the side to which the second spring guide wire 42 (43), now tensioned, is attached. By rotating handle 12 180 degrees, the flexible tip 29 is brought to an opposite portion of the plane in which it was being flexed. Note that such rotation is made possible by the rigidity of main tube portion 23, 24. The flexible tip 29 can then be flexed 180 degrees to one side in this portion of a plane by control 51 in a manner similar to that previously described. In this fashion, flexible tip 29 can be flexed through 360 degrees and provide any necessary angle of view (see Col. 7, Lines 5-35). Thus, it would have been obvious to one skilled in the art at the time the invention was made to provide the apparatus of Ouchi et al. with an articulating section and a control section to control the insertion section, thus allowing a physician any necessary angle of view within a body channel of the patient as taught by Cho et al. and is well known within the art.

Furthermore, Ouchi et al. are silent with respect to the specifics of the overall length of the endoscope tube. Ouchi et al. merely teach of a flexible tube for use in an endoscope, but fail to teach of an overall length of such a device. Cho et al. teach that the overall length of the shaft is about 37-44 cm. The distal stage 23 of the endoscope shaft is preferably about 5-12 cm long with an outer diameter of about 2.4 mm. The middle stage 21 is preferably 10-13 cm long with an outside diameter of about 3 mm. The proximal stage 19 is preferably about 20-23 cm long with an outer diameter of about 3.8 mm. With the above dimensional ranges, the step between the distal-most and middle stages is in the distal third of the shaft (See Col.4, Lines 19-35). Thus, Cho et al. teach of a desirable overall working length of the endoscopic shaft for endoscopic procedures within the urinary system. Thus, if the endoscopic tube of Ouchi et al. is constructed to have a length of 37-44 cm, as taught by Cho et al., then the tapered portion would be located 45cm or less from the distal end of the endoscope.

In regards to claim 18, Ouchi et al. a flexible tube for use in an endoscope, wherein the thickness of the sheathing resin is varied in order to form the small-diameter portion 3c, the large-diameter portion 3f, and the tapered portion 3d-e; and the sheathing resin has an inner diameter formed to be constant over the small-diameter portion, the large-diameter portion, and the tapered portion (see Fig. 5 and Col. 7, Lines 10-15). As seen in figure 5, the inner diameter (not labeled) is clearly a constant diameter over the length of the tube. **In regard to claim 20,** Ouchi et al. teach that sections 33c-f are integrally bonded to form a single integral member, resulting in a continuous seamless outer surface (see Col. 7, Lines 20-35). It is an objective of Ouchi

et al. to fuse the segments together and integrally bond them to the tubular core structure to ensure a flexible tube having a smooth outer surface which can be flexed in conformity with a curved path presented by the organ within the body cavity (see Coll. 87, Lines 15-20). Furthermore, the term "integral" is sufficiently broad to embrace constructions united by such means as fastening and welding (in re Hotte (C.C.P.A.) 157 U.S.P.Q. 326); the term is not necessarily restricted to a one-piece article (in re Kohno (C.C.P.A.) 157 U.S.P.Q. 275); and may be construed as relatively broad (in re Dike (C.C.P.A.) 157 U.S.P.Q. 581). By definition integral means, consisting or composed of parts that together constitute a whole (see http://dictionary.reference.com/browse/integral). Thus, as broadly as claimed, the sheathing of Ouchi et al. meets the current limitations of the instant invention as it is an integral member having a thickness which is varied.

In regards to claim 19, Ouchi et al. fail to specifically teach of a tube wherein the small-diameter portion and the large diameter portion each have a *substantially* constant outer diameter over their respective length. Cho et al. teach of an analogous apparatus having an endoscope shaft which changes in thickness and is preferably in stages 19, 21, 23 of different constant outside diameter. Stages 19, 21, 23 each have different outside diameters that are constant over their entire length, with the most distal end having the smallest outside diameter and the most proximal end having the largest outside diameter (see Fig. 2 and Col. 5, Lines 1-10). Furthermore, Figs. 5a and 5b show two possible combinations of the step-tapered and the uniformly tapered design concepts. In FIG. 5a, the shaft 60 has a proximal step portion 62 of constant outside

diameter, connected to a uniformly tapered distal portion 66. FIG. 5b shows a shaft 68 with a uniformly tapered proximal end 70 connected to a distal stage 72 of constant outer diameter. It is apparent that a number of different combinations of shaft portions are possible, and the preferred embodiments described are for illustration only (see Col. 5, Lines 57-67). It would have been obvious to one skilled in the art at the time the invention was made to provide the small-diameter and large-diameter sections in the apparatus of Ouchi et al. with a constant diameter to provide an alternative embodiment wherein the varying outer diameter of the endoscope dilates canals into which the endoscope is inserted. The thin distal end penetrates and dilates subject body canals to a degree which allows the wider portions of the device to easily follow. Ultimately, such design allows for dilation that is gradual and hence less traumatic than with existing devices as taught by Cho et al.

Claims 5-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,690,175 to Ouchi et al. in view of U.S. Patent No. 5,083,549 to Cho et al. in further view of U.S. Patent No. 5,084,022 to Claude.

In regards to claims 5-8, Ouchi et al. and Cho et al. disclose an apparatus having an articulating section, a control section and large and small diameter portions connected via a tapered portion (see above rejection) but are silent with respect to indices indicating distances from the distal end are inscribed on the soft portion and the specifics of where indices may be inscribed along the soft portion. Claude teaches of an analogous medical apparatus provided with spaced indicia to indicate the distance the instrument is extended into a vascular vessel, catheter or other instrument (see Figs. 1-

3 and 6). **In regard to claims 9-12**, Claude teaches of an apparatus wherein the indices are inscribed equidistantly along the apparatus (see Col. 2, Lines 33-36). **In regard to claims 13-16,** the indices may be formed on the instrument in any desired location considered to be helpful to the operator and the desired procedure and may be formed over the entire length of the apparatus (see Figs 4-5 and Col. 5, Lines 1-9). It would have been obvious to one skilled in the art at the time the invention was made to include indices on the apparatus of Ouchi et al. and Cho et al. in order to facilitate the determination of the distance an instrument extends into a cavity as taught by Claude.

Response to Arguments

Applicant's arguments filed October 29, 2008 have been fully considered but they are not persuasive.

Applicant states that neither Boury nor Ouchi et al. teach of a tapered portion located 70 cm or less from the distal end of the insertion tube. Examiner disagrees. Ouchi et al. merely teach of a flexible tube for use in an endoscope, but fail to teach of an overall length of such a device and are silent with respect to the specifics of the overall length of the endoscope tube. Boury teach that the overall length of the catheter may be varied as necessary. For some procedures, the catheter can be fairly short as the distance between the insertion point into a patient's vessel and the target site is relatively short. In other circumstances, the catheter may be required to traverse a relatively long path, such as in reaching a remote site in a patient's vasculature. Accordingly, depending on the class of procedures for which the catheter is intended, the length can vary considerably. However, typical catheter lengths will be on the order

of about 50-150 cm, with the range being narrower for catheters intended to access a particular region. For example, abdominal and renal catheters are typically on the order of about 50-70 cm while intracranial catheters are usually longer, with lengths of about 100-125 cm being most common (See Col. 4, Lines 6-20). Thus, Boury teach that the overall length of the endoscope shaft is variable depending upon the surgical procedure being performed. If the flexible tube of Ouchi et al. is constructed to have an overall length of about 50-70 cm for a renal procedure, as taught by Boury, then the tapered would have to be located 70cm or less from the distal end of the endoscope as the entire length of the endoscope shaft would be no more than 70 cm. As broadly as claimed, the combination of Boury and Ouch et al. meet the limitations of the recited claims.

Furthermore, Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739

1/7/09